

PART 1 – GENERAL INFORMATION

This is a Combined Synopsis/Solicitation for Commercial Items prepared in accordance with the format in FAR Subpart 12.6 and 13.5. This Request for Quotation (RFQ) announcement constitutes the only solicitation that will be issued; quotes are being requested and a written solicitation will not be issued. This requirement is being solicited as a total small business set aside and the Government contemplates a Labor Hour Purchase Order will result from this solicitation. The solicitation document and incorporated provisions and clauses are those in effect through Federal Acquisition Circular 05-81 dated April 10, 2015.

The associated North American Industrial Classification System (NAICS) code for this procurement is 541511. Its associated Small Business Size Standard is \$27.5 Million.

PART 2 – SUPPLIES OR SERVICES AND PRICES/COSTS

Description of Supplies or Services

The Food & Drug Administration's Center for Biologics, Evaluation and Research (CBER) and Center for Drugs, Evaluation and Research (CDER) require a contract for Empirica Signal consulting services for a six month period.

Contractor site rates should be applied to this purchase order.

PART 3 – DESCRIPTION

The following is a description of the requirements under this service contract:

A. Project Administration

1. Meeting Management

Scope:

- a) The contractor shall schedule and host bi-weekly CDER/CBER Empirica Signal status meetings (via teleconference) with a maximum duration of 1 hour. The contractor shall draft and store the meeting minutes in the CDER Data Mining Projects SharePoint Site (SPS).
- b) The contractor shall schedule and host separate monthly CBER-focused Empirica Signal status meetings (via teleconference) with a maximum duration of 1 hour. The contractor shall draft and email the meeting minutes.

Project Assumptions:

- a) For bi-weekly CDER/CBER Empirica Signal status meetings, FDA participants will include core members of the CDER/CBER data mining team. For the monthly CBER-focused Empirica Signal status meetings FDA participants will include core members of the CBER data mining team.

2. Status Reports

Scope:

- a) The contractor shall prepare and deliver separate monthly status reports to CDER and CBER. The reports will detail deliverables, data and Signal Management refreshes, infrastructure status, pending/future service activities, support issues, and product name mapping and Signal Management modifications during the reporting period.
- b) The contractor shall store the CDER status reports in the CDER Data Mining Projects SPS and email the reports to the CBER team.

Project Assumptions:

The status reports will be delivered by the seventh day of the following month.

B. Operations & Maintenance

1. Data (Database) Administration

Scope:

- a) The contractor shall provide Empirica Signal related database and application operations and maintenance services to ensure the availability of Empirica Signal to CDER and CBER users. Database administration services will include server issue identification, analysis and appropriate resolution in the Empirica Signal production environment.
- b) The contractor shall coordinate with the FDA OIM DBA to follow established OIM processes in the Empirica production environment.

Out of Scope:

- a) The contractor shall not provide software/hardware update, application upgrade or server migration support during this continuation period.

Government Obligation:

- a) The FDA will supply the appropriate Office of Information Management (OIM) Database Administrator (DBA) and system administration support.

2. Data, Standard Runs and Signal Management Refresh

Scope:

- a) The contractor shall perform standard data preparation activities including data ETL (Extract-Transform-Load), validation, error checking, time stamping, product name standardization/coding, and duplicate removal. MedDRA updates will be implemented when event terms from the latest MedDRA version appear in the FAERS/CBAERS or VAERS data. The contractor shall confirm that the data preparation process has been executed.
- b) Following the data preparation activities, the contractor shall refresh the FAERS/CBAERS and CBER VAERS data and standard runs (19 FAERS runs and 16 VAERS runs) on a weekly basis and the FAERS and VAERS Signal Management runs and views on a monthly basis.

Out of Scope:

- a) No changes in the data preparation process will be initiated or implemented during this continuation period.
- b) Empirica Signal configuration, data field or standard run additions or modifications will not be conducted during this continuation period.

Government Obligations:

- a) The FDA will be responsible for providing FAERS/CBAERS and VAERS data extracts for the contractor to load and process the data.
- b) Additional drugs or vaccines to be incorporated into Signal Management will be supplied by CDER or CBER, respectively.

3. Product Name Data Management

Scope:

- a) The contractor shall map product name verbatims to the appropriate generic and trade name in accordance with the existing mapping standardization process, maintain product name standardization to account for corrections, concatenated terms, custom terms, and product categories, and maintain the corresponding data dictionaries.
- b) The contractor shall perform product name mapping updates on a monthly basis, coordinated with the Signal Management refresh processes.
- c) The contractor shall schedule and host bi-weekly CDER/CBER Empirica Signal status meetings (via teleconference) with a maximum duration of 1 hour. The contractor shall draft and store the meeting minutes in the CDER Data Mining Projects SharePoint Site (SPS).
- d) The contractor shall schedule and host separate monthly CBER-focused Empirica Signal status meetings (via teleconference) with a maximum duration of 1 hour. The contractor shall draft and email the meeting minutes.

Project Assumptions:

For bi-weekly CDER/CBER Empirica Signal status meetings, FDA participants will include core members of the CDER/CBER data mining team. For the monthly CBER-focused Empirica Signal status meetings FDA participants will include core members of the CBER data mining team.

4. Status Reports

Scope:

- a) The contractor shall prepare and deliver separate monthly status reports to CDER and CBER. The reports will detail deliverables, data and Signal Management refreshes, infrastructure status, pending/future service activities, support issues, and product name mapping and Signal Management modifications during the reporting period.
- b) The contractor shall store the CDER status reports in the CDER Data Mining Projects SPS and email the reports to the CBER team.

Project Assumptions:

The status reports will be delivered by the seventh day of the following month.

C. Operations & Maintenance

1. Data (Database) Administration

Scope:

- a) The contractor shall provide Empirica Signal related database and application operations and maintenance services to ensure the availability of Empirica Signal to CDER and CBER users. Database administration services will include server issue identification, analysis and appropriate resolution in the Empirica Signal production environment.
- b) The contractor shall coordinate with the FDA OIM DBA to follow established OIM processes in the Empirica production environment.

Out of Scope:

The contractor shall not provide software/hardware update, application upgrade or server migration support during this continuation period.

Government Obligation:

The FDA will supply the appropriate Office of Information Management (OIM) Database Administrator (DBA) and system administration support.

2. Data, Standard Runs and Signal Management Refresh

Scope:

- a) The contractor shall perform standard data preparation activities including data ETL (Extract-Transform-Load), validation, error checking, time stamping, product name standardization/coding, and duplicate removal. MedDRA updates will be implemented when event terms from the latest MedDRA version appear in the FAERS/CBAERS or

VAERS data. The contractor shall confirm that the data preparation process has been executed.

- b) Following the data preparation activities, the contractor shall refresh the FAERS/CBAERS and CBER VAERS data and standard runs (19 FAERS runs and 16 VAERS runs) on a weekly basis and the FAERS and VAERS Signal Management runs and views on a monthly basis.

Out of Scope:

- a) No changes in the data preparation process will be initiated or implemented during this continuation period.
- b) Empirica Signal configuration, data field or standard run additions or modifications will not be conducted during this continuation period.

Government Obligations:

- a) The FDA will be responsible for providing FAERS/CBAERS and VAERS data extracts for the contractor to load and process the data.
- b) Additional drugs or vaccines to be incorporated into Signal Management will be supplied by CDER or CBER, respectively.

3. Product Name Data Management

Scope:

- a) The contractor shall map product name verbatims to the appropriate generic and trade name in accordance with the existing mapping standardization process, maintain product name standardization to account for corrections, concatenated terms, custom terms, and product categories, and maintain the corresponding data dictionaries.
- b) The contractor shall perform product name mapping updates on a monthly basis, coordinated with the Signal Management refresh processes.

Government Obligations:

- a) CDER will be responsible for providing newly FDA-approved drug names for mapping and the contractor shall conduct the verbatim mapping and incorporation into Signal Management, where appropriate.
- b) CBER may provide guidance into the appropriate mapping of therapeutic biologics.

| Performance | Deliverable | Timeframe |
|-------------|-------------|-----------|
| | | |

| | | |
|--------------------|---|----------------------------------|
| Project Management | Status Report as described in the task order Detailed invoice, based on the contract line item numbers in the contract | Reported monthly |
| Project Management | The contractor shall schedule and host bi-weekly CDER/CBER Empirica Signal status meetings (via teleconference) with a maximum duration of 1 hour. The contractor shall draft and store the meeting minutes in the CDER Data Mining Projects SharePoint Site (SPS). | Weekly |
| Project Management | The contractor shall schedule and host separate monthly CBER-focused Empirica Signal status meetings (via teleconference) with a maximum duration of 1 hour. The contractor shall draft and email the meeting minutes. | Monthly |
| Project Management | The contractor shall store the CDER status reports in the CDER Data Mining Projects SPS and email the reports to the CBER team. | Weekly |
| Project Management | FDA EPLC templates may be used or referenced: (R03) Systems Concept of Operations (CONOPS) and/or Systems Overview Sheet (DS03) Interface Control Document (ICD) (T09) Performance Test Report (T12) Operation and Maintenance Manual Communication plan | Three weeks after contract award |
| O&M Support | <ul style="list-style-type: none"> Tools management plan Archival plan Product name standardization plan | Three weeks after contract award |
| | <ul style="list-style-type: none"> Data refreshes of FAERS and VAERS data | Weekly |

| | | |
|-------------|--|-----------|
| O&M Support | Core Signal Management Functionality <ul style="list-style-type: none"> • Computation of MGPS signal scores for all drug-event combinations involving drugs monitored | Monthly |
| | <ul style="list-style-type: none"> • Initial Quality Assurance Plan and Plan | Quarterly |

4. **Ad-hoc Consulting Assistance**

Scope:

- a) The contractor shall provide up to five (5) person days of consulting assistance to address Empirica Signal “ad hoc” requests. The assistance may include performing the following activities:
 1. Performing Signal Management reviewer assignments in the Empirica Signal application (to minimize the time to execute this activity, the contractor shall advise that the requestor specifies the standard drug name currently in Signal Management, where appropriate, as opposed to the drug name from the FAERS product assignment list).
 2. Other requests that may be captured under this category include assistance with data mining runs, reports, queries or other Empirica Signal functionalities.

Additional Out of Scope Activities

The activities listed below are excluded from the assumed scope of services. The excluded activities are provided as a point of reference and are not intended to be an exhaustive list. Some of these activities may be performed by FDA project staff. Any or all can be added to this project at an additional cost:

- Methodology validation activities
- Configuration control board (“CCB”) activities
- Communication plan activities
- EPLC documentation updates
- CDER Duplicate Removal Management (i.e. algorithm changes)
- Archival process development
- Development and delivery of any training

PART 4 – PACKING, MARKING AND SHIPPING

All deliverables required under this contract shall be packaged, marked and shipped in accordance with Government specifications. At a minimum, all deliverables shall be marked with the contract/order number and contractor name. The contractor shall guarantee that all required materials shall be delivered in immediate usable and acceptable condition.

PART 5 – INSPECTION AND ACCEPTANCE

The Contracting Officer will perform inspection and acceptance of equipment, installation and services to be provided. The Contracting Officer – to be determined upon contract award - is the authorized representative of the Contracting Officer.

PART 6 – DELIVERIES OR PERFORMANCE

Period of Performance

The services shall be performed six months from the date of contract award.

PART 7 – CONTRACT ADMINISTRATION DATA

a. The following personnel will represent the Government for the purpose of this contract:

1. Contracting Officers Representative (COR):

Bruce Weaver
10903 New Hampshire Avenue
Building 21, Room 4508
White Oak, MD 20993

The COR is responsible for: (1) monitoring the Contractor's technical progress, including the surveillance and assessment of performance and recommending to the Contracting Officer changes in requirements; (2) interpreting the Statement of Work (SOW) and any other technical performance requirements; (3) performing technical evaluation as required; (4) performing technical inspections and acceptances required by this contract; and (5) assisting in the resolution of technical problems encountered during performance.

2. Contract Specialist (Primary POC)

DeLane Jones
5630 Fishers Lane, Room 2090
Rockville, MD 20857
Delane.jones@fda.hhs.gov
Tel: (240) 402-7665

3. Contracting Officer (Alt. POC)

Brendan McCarthy
5630 Fishers Lane, Room 2099

Rockville, MD 20857

Brendan.McCarthy@fda.hhs.gov

Tel: (240) 402-7540

The Contracting Officer is the only person with authority to act as agent of the Government under this contract. Only the Contracting Officer has authority to: (1) direct or negotiate any changes in the RFQ; (2) modify or extend the period of performance; (3) change the delivery schedule; (4) authorize reimbursement to the Contractor any costs incurred during the performance of this contract; or (5) otherwise change any terms and conditions of this contract.

b. Two-Way Invoicing Instructions

A. The Contractor shall submit all invoices to all addressees in the manner specified below:

- (I) One original and one copy to the approving official:
U.S. FOOD AND DRUG ADMINISTRATION
OFFICE OF ACQUISITIONS AND GRANTS SERVICES
5630 Fishers Lane, Room 2090
Attention: DeLane Jones, Delane.jones@fda.hhs.gov
Rockville, MD 20857

*** ACCEPTABLE METHODS OF DELIVERY INCLUDE: MAIL OR HAND DELIVERY

- (II) One copy to the contracting officer representative (COR) or other program center/office designee clearly marked "courtesy copy only":

U.S. FOOD AND DRUG ADMINISTRATION
10903 New Hampshire Avenue
Building 21, Room 4508
Attention: Bruce Weaver, Bruce.Weaver@fda.hhs.gov
White Oak, MD 20903

*** Acceptable methods of delivery include: mail, hand delivery, or e-mail

B. Invoices submitted under this contract must comply with the requirements set forth in FAR Clauses 52.232-25 (Prompt Payment) and 52.232-33 (Payment by Electronic Funds Transfer – Central Contractor Registration) and/or other applicable FAR clauses specified herein. To constitute a proper invoice, the invoice must be submitted on company letterhead and include each of the following:

- (I) Name and address of the Contractor; (ii)
Invoice date and invoice number;
(iii) Purchase order/award number;
- (iv) Description, quantity, unit of measure, unit price, and extended price supplies delivered or services performed, including:
- (a) period of performance for which costs are claimed;
 - (b) itemized travel costs, including origin and destination;
 - (c) any other supporting information necessary to clarify questionable expenditures;

(v) Shipping number and date of shipment, including the bill of lading number and weight of shipment if shipped on government bill of lading;

(vi) Terms of any discount for prompt payment offered;

(vii) Name and address of official to whom payment is to be sent (must be the same as that in the purchase order/award, or in a proper notice of assignment);

(viii) Name, title, and phone number of person to notify in event of defective invoice; (ix) Taxpayer identification number (TIN);

(x) Electronic funds transfer (EFT) banking information, including routing transit number of the financial institution receiving payment and the number of the account into which funds are to be deposited;

(xi) Name and telephone number of the FDA contracting officer technical representative (COR) or other program center/office point of contact, as referenced on the purchase order;

(xii) Any other information or documentation required by the purchase order/award.

(xiii) Contractor is required to attach an invoice log addendum to each invoice which shall include, at a minimum, the following information for contract administration and reconciliation purposes:

(a) list of all invoices submitted to date under the subject award, including the following:

(1) invoice number, amount, & date submitted

(2) corresponding payment amount & date received

(b) total amount of all payments received to date under the subject contract or order

(c) and, for definitized contracts or orders only, total estimated amounts yet to be invoiced for the current, active period of performance

C. An electronic invoice is not accepted.

D. Questions regarding invoice payments should be directed to the FDA Payment Office at:
Food and Drug Administration/ Office of Financial Services
10903 New Hampshire Ave
WO32 - Second Floor, MAIL HUB 2145
Silver Spring, MD 20993-0002
Attn: Vendor Payments
Phone 301-827-ERIC (3742)

E. Invoices shall be submitted after the submission of the monthly status reports and monthly financial reports

PART 8 – SPECIAL CONTRACT REQUIREMENTS

Government Holidays

Workplace is not available on the Government Holidays stated below, or as prescribed by an Executive Order (EO) or OPM.gov due to inclement weather.

January New Year's Day

| | |
|-----------|------------------------|
| January | Martin Luther King Day |
| February | President's Day |
| May | Memorial Day |
| July | Independence Day |
| September | Labor Day |
| October | Columbus Day |
| November | Veterans Day |
| November | Thanksgiving |
| December | Christmas Day |

Contractor Performance Evaluations

In accordance with FAR 42.15, FDA will complete annual and final Contractor performance evaluations. Annual evaluations will be prepared to coincide with the anniversary date of the award. Additional interim performance evaluations may be prepared at the FDA's Contracting Officer discretion, as necessary. Final performance evaluations will be completed upon expiration of the contract.

FDA will utilize the Contractor Performance Assessment Reporting System (CPARS) to execute annual and final Contractor performance evaluations. CPARS is a secure Internet website located at the following address: <https://cpars.cpars.gov/>. FDA will register the Contractor in CPARS upon receipt of the names and email addresses of two individuals who will be responsible for serving as the Contractor's primary and alternate CPARS contacts. Once FDA registers the Contractor in CPARS, the Contractor will receive an automated CPARS email message which contains user identification information and instructions for creating a password.

Once a performance evaluation is issued, the Contractor's primary and alternate CPARS contacts will receive an email instructing them to access CPARS to review the performance evaluation. The Contractor has 14 days from the date of performance evaluation issuance in which to review the evaluation. If the Contractor is in agreement with the performance evaluation outcome, the evaluation becomes final. Should the Contractor be in disagreement with the performance evaluation outcome, the Contractor shall submit rebuttal comments via CPARS within 14 days from the date the evaluation was issued by the FDA. Any disagreement between the Contracting Officer and the Contractor will be referred to a contracting official one level above the Contracting Officer, whose decision will be final.

Copies of each performance evaluation and Contractor responses, if any, will be retained as part of the official contract file and will be used to support future award decisions. Evaluations will also be stored for a three year period in the Past Performance Information Retrieval System (PPIRS) at www.ppirs.gov.

The Contractor may obtain CPARS training material and register for on-line training at the following website: <https://www.cpars.gov/allapps/cpcbtdlf.htm>. There is no fee for registration or use of CPARS.

PART 9 - CONTRACT CLAUSES

FAR 52.252-2 Clauses Incorporated by Reference (Feb. 1998)

This contract incorporates one or more clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at this/these address(es): FAR: <http://farsite.hill.af.mil/vffara.htm>, HHSAR: <http://farsite.hill.af.mil/VFHHSARA.HTM>.

FAR 52.212-1 Instructions to Offerors – Commercial Items (Oct. 2015)

FAR 52.212-2 Evaluation – Commercial Items (Oct. 2014)

FAR 52.212-3 Offeror Representations and Certifications—Commercial Items (Mar. 2016)

FAR 52.212-4 Contract Terms and Conditions—Commercial Items. (May 2015)

HHSAR Clause:

HHSAR 352.239–73 Electronic Information and Technology Accessibility Notice (Dec. 2015)

HHSAR 352.239–74 Electronic Information and Technology Accessibility (Dec. 2015)

FAR 52.212-5 Contract Terms and Conditions Required to Implement Statutes or Executive Orders—Commercial Items (Mar. 2016).

As prescribed in [12.301](#)(b)(4), insert the following clause:

Contract Terms and Conditions Required to Implement Statutes or Executive Orders—Commercial Items (May 2015)

(a) The Contractor shall comply with the following Federal Acquisition Regulation (FAR) clauses, which are incorporated in this contract by reference, to implement provisions of law or Executive orders applicable to acquisitions of commercial items:

(1) [52.209-10](#), Prohibition on Contracting with Inverted Domestic Corporations (Dec 2014)

(2) [52.233-3](#), Protest After Award (Aug 1996) ([31 U.S.C. 3553](#)).

(3) [52.233-4](#), Applicable Law for Breach of Contract Claim (Oct 2004)(Public Laws 108-77 and 108-78 ([19 U.S.C. 3805 note](#))).

(b) The Contractor shall comply with the FAR clauses in this paragraph (b) that the Contracting Officer has indicated as being incorporated in this contract by reference to implement provisions of law or Executive orders applicable to acquisitions of commercial items:

[Contracting Officer check as appropriate.]

 X (1) [52.203-6](#), Restrictions on Subcontractor Sales to the Government (Sept 2006), with Alternate I (Oct 1995) ([41 U.S.C. 4704](#) and [10 U.S.C. 2402](#)).

 (2) [52.203-13](#), Contractor Code of Business Ethics and Conduct (Apr 2010) ([41 U.S.C. 3509](#))).

 (3) [52.203-15](#), Whistleblower Protections under the American Recovery and Reinvestment Act of 2009 (June 2010) (Section 1553 of Pub. L. 111-5). (Applies to contracts funded by the American Recovery and Reinvestment Act of 2009.)

 X (4) [52.204-10](#), Reporting Executive Compensation and First-Tier Subcontract Awards (Jul 2013) (Pub. L. 109-282) ([31 U.S.C. 6101 note](#)).

 (5) [Reserved].

___ (6) [52.204-14](#), Service Contract Reporting Requirements (Jan 2014) (Pub. L. 111-117, section 743 of Div. C).

___ (7) [52.204-15](#), Service Contract Reporting Requirements for Indefinite-Delivery Contracts (Jan 2014) (Pub. L. 111-117, section 743 of Div. C).

X (8) [52.209-6](#), Protecting the Government's Interest When Subcontracting with Contractors Debarred, Suspended, or Proposed for Debarment. (Aug 2013) (31 U.S.C. 6101 note).

___ (9) [52.209-9](#), Updates of Publicly Available Information Regarding Responsibility Matters (Jul 2013) (41 U.S.C. 2313).

___ (10) [Reserved].

___ (11)(i) [52.219-3](#), Notice of HUBZone Set-Aside or Sole-Source Award (Nov 2011) ([15 U.S.C. 657a](#)).

___ (ii) Alternate I (Nov 2011) of [52.219-3](#).

___ (12)(i) [52.219-4](#), Notice of Price Evaluation Preference for HUBZone Small Business Concerns (Oct 2014) (if the offeror elects to waive the preference, it shall so indicate in its offer) ([15 U.S.C. 657a](#)).

___ (ii) Alternate I (Jan 2011) of [52.219-4](#).

___ (13) [Reserved]

___ (14)(i) [52.219-6](#), Notice of Total Small Business Set-Aside (Nov 2011) ([15 U.S.C. 644](#)).

___ (ii) Alternate I (Nov 2011).

___ (iii) Alternate II (Nov 2011).

___ (15)(i) [52.219-7](#), Notice of Partial Small Business Set-Aside (June 2003) ([15 U.S.C. 644](#)).

___ (ii) Alternate I (Oct 1995) of [52.219-7](#).

___ (iii) Alternate II (Mar 2004) of [52.219-7](#).

X (16) [52.219-8](#), Utilization of Small Business Concerns (Oct 2014) ([15 U.S.C. 637\(d\)\(2\)](#) and (3)).

___ (17)(i) [52.219-9](#), Small Business Subcontracting Plan (Oct 2014) ([15 U.S.C. 637\(d\)\(4\)](#)).

___ (ii) Alternate I (Oct 2001) of [52.219-9](#).

___ (iii) Alternate II (Oct 2001) of [52.219-9](#).

___ (iv) Alternate III (Oct 2014) of [52.219-9](#).

___ (18) [52.219-13](#), Notice of Set-Aside of Orders (Nov 2011)([15 U.S.C. 644\(r\)](#)).

- ___ (19) [52.219-14](#), Limitations on Subcontracting (Nov 2011) ([15 U.S.C. 637\(a\)\(14\)](#)).
- ___ (20) [52.219-16](#), Liquidated Damages—Subcontracting Plan (Jan 1999) ([15 U.S.C. 637\(d\)\(4\)\(F\)\(i\)](#)).
- ___ (21) [52.219-27](#), Notice of Service-Disabled Veteran-Owned Small Business Set-Aside (Nov 2011) ([15 U.S.C. 657 f](#)).
- X (22) [52.219-28](#), Post Award Small Business Program Representation (Jul 2013) ([15 U.S.C. 632\(a\)\(2\)](#)).
- ___ (23) [52.219-29](#), Notice of Set-Aside for Economically Disadvantaged Women-Owned Small Business (EDWOSB) Concerns (Jul 2013) ([15 U.S.C. 637\(m\)](#)).
- ___ (24) [52.219-30](#), Notice of Set-Aside for Women-Owned Small Business (WOSB) Concerns Eligible Under the WOSB Program (Jul 2013) ([15 U.S.C. 637\(m\)](#)).
- X (25) [52.222-3](#), Convict Labor (June 2003) (E.O. 11755).
- X (26) [52.222-19](#), Child Labor—Cooperation with Authorities and Remedies (Jan 2014) (E.O. 13126).
- X (27) [52.222-21](#), Prohibition of Segregated Facilities (Apr 2015).
- X (28) [52.222-26](#), Equal Opportunity (Apr 2015) (E.O. 11246).
- X (29) [52.222-35](#), Equal Opportunity for Veterans (Jul 2014)([38 U.S.C. 4212](#)).
- X (30) [52.222-36](#), Equal Opportunity for Workers with Disabilities (Jul 2014) ([29 U.S.C. 793](#)).
- X (31) [52.222-37](#), Employment Reports on Veterans (Jul 2014) ([38 U.S.C. 4212](#)).
- ___ (32) [52.222-40](#), Notification of Employee Rights Under the National Labor Relations Act (Dec 2010) (E.O. 13496).
- X (33) (i) [52.222-50](#), Combating Trafficking in Persons (Mar 2015) ([22 U.S.C. chapter 78](#) and E.O. 13627).
- ___ (ii) Alternate I (Mar 2015) of [52.222-50](#) ([22 U.S.C. chapter 78](#) and E.O. 13627).
- X (34) [52.222-54](#), Employment Eligibility Verification (Aug 2013). (Executive Order 12989). (Not applicable to the acquisition of commercially available off-the-shelf items or certain other types of commercial items as prescribed in [22.1803](#).)
- ___ (35) (i) [52.223-9](#), Estimate of Percentage of Recovered Material Content for EPA–Designated Items (May 2008) ([42 U.S.C. 6962\(c\) \(3\) \(A\) \(ii\)](#)). (Not applicable to the acquisition of commercially available off-the-shelf items.)
- ___ (ii) Alternate I (May 2008) of [52.223-9](#) ([42 U.S.C. 6962\(i\) \(2\) \(C\)](#)). (Not applicable to the acquisition of commercially available off-the-shelf items.)

___ (36) (i) [52.223-13](#), Acquisition of EPEAT®-Registered Imaging Equipment (Jun 2014) (E.O.s 13423 and 13514).

___ (ii) Alternate I (Jun 2014) of [52.223-13](#).

___ (37) (i) [52.223-14](#), Acquisition of EPEAT®-Registered Televisions (Jun 2014) (E.O.s 13423 and 13514).

___ (ii) Alternate I (Jun 2014) of [52.223-14](#).

___ (38) [52.223-15](#), Energy Efficiency in Energy-Consuming Products (Dec 2007) ([42 U.S.C. 8259b](#)).

___ (39) (i) [52.223-16](#), Acquisition of EPEAT®-Registered Personal Computer Products (Jun 2014) (E.O.s 13423 and 13514).

___ (ii) Alternate I (Jun 2014) of [52.223-16](#).

X (40) [52.223-18](#), Encouraging Contractor Policies to Ban Text Messaging While Driving (Aug 2011) (E.O. 13513).

X (41) [52.225-1](#), Buy American—Supplies (May 2014) ([41 U.S.C. chapter 83](#)).

X (42)(i) [52.225-3](#), Buy American—Free Trade Agreements—Israeli Trade Act (May 2014) ([41 U.S.C. chapter 83](#), [19 U.S.C. 3301](#) note, [19 U.S.C. 2112](#) note, [19 U.S.C. 3805](#) note, [19 U.S.C. 4001](#) note, Pub. L. 103-182, 108-77, 108-78, 108-286, 108-302, 109-53, 109-169, 109-283, 110-138, 112-41, 112-42, and 112-43).

___ (ii) Alternate I (May 2014) of [52.225-3](#).

___ (iii) Alternate II (May 2014) of [52.225-3](#).

___ (iv) Alternate III (May 2014) of [52.225-3](#).

___ (43) [52.225-5](#), Trade Agreements (Nov 2013) ([19 U.S.C. 2501](#), et seq., [19 U.S.C. 3301](#) note).

X (44) [52.225-13](#), Restrictions on Certain Foreign Purchases (June 2008) (E.O.'s, proclamations, and statutes administered by the Office of Foreign Assets Control of the Department of the Treasury).

___ (45) [52.225-26](#), Contractors Performing Private Security Functions Outside the United States (Jul 2013) (Section 862, as amended, of the National Defense Authorization Act for Fiscal Year 2008; [10 U.S.C. 2302 Note](#)).

___ (46) [52.226-4](#), Notice of Disaster or Emergency Area Set-Aside (Nov 2007) ([42 U.S.C. 5150](#)).

___ (47) [52.226-5](#), Restrictions on Subcontracting Outside Disaster or Emergency Area (Nov 2007) ([42 U.S.C. 5150](#)).

___ (48) [52.232-29](#), Terms for Financing of Purchases of Commercial Items (Feb 2002) ([41 U.S.C. 4505](#), [10 U.S.C. 2307\(f\)](#)).

___ (49) [52.232-30](#), Installment Payments for Commercial Items (Oct 1995) ([41 U.S.C. 4505](#), [10 U.S.C. 2307\(f\)](#)).

X (50) [52.232-33](#), Payment by Electronic Funds Transfer—System for Award Management (Jul 2013) ([31 U.S.C. 3332](#)).

___ (51) [52.232-34](#), Payment by Electronic Funds Transfer—Other than System for Award Management (Jul 2013) ([31 U.S.C. 3332](#)).

___ (52) [52.232-36](#), Payment by Third Party (May 2014) ([31 U.S.C. 3332](#)).

___ (53) [52.239-1](#), Privacy or Security Safeguards (Aug 1996) ([5 U.S.C. 552a](#)).

___ (54)(i) [52.247-64](#), Preference for Privately Owned U.S.-Flag Commercial Vessels (Feb 2006) ([46 U.S.C. Appx. 1241\(b\)](#) and [10 U.S.C. 2631](#)).

___ (ii) Alternate I (Apr 2003) of [52.247-64](#).

(c) The Contractor shall comply with the FAR clauses in this paragraph (c), applicable to commercial services, that the Contracting Officer has indicated as being incorporated in this contract by reference to implement provisions of law or Executive orders applicable to acquisitions of commercial items:

[Contracting Officer check as appropriate.]

___ (1) [52.222-17](#), Nondisplacement of Qualified Workers (May 2014) (E.O. 13495).

___ (2) [52.222-41](#), Service Contract Labor Standards (May 2014) ([41 U.S.C. chapter 67](#)).

___ (3) [52.222-42](#), Statement of Equivalent Rates for Federal Hires (May 2014) ([29 U.S.C. 206](#) and [41 U.S.C. chapter 67](#)).

X (4) [52.222-43](#), Fair Labor Standards Act and Service Contract Labor Standards-Price Adjustment (Multiple Year and Option Contracts) (May 2014) ([29 U.S.C. 206](#) and [41 U.S.C. chapter 67](#)).

___ (5) [52.222-44](#), Fair Labor Standards Act and Service Contract Labor Standards—Price Adjustment (May 2014) ([29 U.S.C. 206](#) and [41 U.S.C. chapter 67](#)).

___ (6) [52.222-51](#), Exemption from Application of the Service Contract Labor Standards to Contracts for Maintenance, Calibration, or Repair of Certain Equipment—Requirements (May 2014) ([41 U.S.C. chapter 67](#)).

___ (7) [52.222-53](#), Exemption from Application of the Service Contract Labor Standards to Contracts for Certain Services—Requirements (May 2014) ([41 U.S.C. chapter 67](#)).

___ (8) [52.222-55](#), Minimum Wages Under Executive Order 13658 (Dec 2014) (E.O. 13658).

___ (9) [52.226-6](#), Promoting Excess Food Donation to Nonprofit Organizations (May 2014) ([42 U.S.C. 1792](#)).

___ (10) [52.237-11](#), Accepting and Dispensing of \$1 Coin (Sept 2008) ([31 U.S.C. 5112\(p\) \(1\)](#)).

(d) Comptroller General Examination of Record. The Contractor shall comply with the provisions of this paragraph (d) if this contract was awarded using other than sealed bid, is in excess of the simplified acquisition threshold, and does not contain the clause at [52.215-2](#), Audit and Records—Negotiation.

(1) The Comptroller General of the United States, or an authorized representative of the Comptroller General, shall have access to and right to examine any of the Contractor's directly pertinent records involving transactions related to this contract.

(2) The Contractor shall make available at its offices at all reasonable times the records, materials, and other evidence for examination, audit, or reproduction, until 3 years after final payment under this contract or for any shorter period specified in FAR [Subpart 4.7](#), Contractor Records Retention, of the other clauses of this contract. If this contract is completely or partially terminated, the records relating to the work terminated shall be made available for 3 years after any resulting final termination settlement. Records relating to appeals under the disputes clause or to litigation or the settlement of claims arising under or relating to this contract shall be made available until such appeals, litigation, or claims are finally resolved.

(3) As used in this clause, records include books, documents, accounting procedures and practices, and other data, regardless of type and regardless of form. This does not require the Contractor to create or maintain any record that the Contractor does not maintain in the ordinary course of business or pursuant to a provision of law.

(e)(1) Notwithstanding the requirements of the clauses in paragraphs (a), (b), (c), and (d) of this clause, the Contractor is not required to flow down any FAR clause, other than those in this paragraph (e)(1) in a subcontract for commercial items. Unless otherwise indicated below, the extent of the flow down shall be as required by the clause—

(i) [52.203-13](#), Contractor Code of Business Ethics and Conduct (Apr 2010) ([41 U.S.C. 3509](#)).

(ii) [52.219-8](#), Utilization of Small Business Concerns (Oct 2014) ([15 U.S.C. 637\(d\) \(2\)](#) and (3)), in all subcontracts that offer further subcontracting opportunities. If the subcontract (except subcontracts to small business concerns) exceeds \$650,000 (\$1.5 million for construction of any public facility), the subcontractor must include [52.219-8](#) in lower tier subcontracts that offer subcontracting opportunities.

(iii) [52.222-17](#), Nondisplacement of Qualified Workers (May 2014) (E.O. 13495). Flow down required in accordance with paragraph (l) of FAR clause [52.222-17](#).

(iv) [52.222-21](#), Prohibition of Segregated Facilities (Apr 2015)

(v) [52.222-26](#), Equal Opportunity (Apr 2015) (E.O. 11246).

(vi) [52.222-35](#), Equal Opportunity for Veterans (Jul 2014) ([38 U.S.C. 4212](#)).

- (vii) [52.222-36](#), Equal Opportunity for Workers with Disabilities (Jul 2014) ([29 U.S.C. 793](#)).
- (viii) [52.222-37](#), Employment Reports on Veterans (Jul 2014) ([38 U.S.C. 4212](#))
- (ix) [52.222-40](#), Notification of Employee Rights Under the National Labor Relations Act (Dec 2010) (E.O. 13496). Flow down required in accordance with paragraph (f) of FAR clause [52.222-40](#).
- (x) [52.222-41](#), Service Contract Labor Standards (May 2014) ([41 U.S.C. chapter 67](#)).
- (xi)
- _X_ (A) [52.222-50](#), Combating Trafficking in Persons (Mar 2015) ([22 U.S.C. chapter 78](#) and E.O 13627).
- ___ (B) Alternate I (Mar 2015) of [52.222-50](#) ([22 U.S.C. chapter 78 and E.O 13627](#)).
- (xii) [52.222-51](#), Exemption from Application of the Service Contract Labor Standards to Contracts for Maintenance, Calibration, or Repair of Certain Equipment-Requirements (May 2014) ([41 U.S.C. chapter 67](#)).
- (xiii) [52.222-53](#), Exemption from Application of the Service Contract Labor Standards to Contracts for Certain Services-Requirements (May 2014) ([41 U.S.C. chapter 67](#)).
- (xiv) [52.222-54](#), Employment Eligibility Verification (Aug 2013).
- (xv) [52.222-55](#), Minimum Wages Under Executive Order 13658 (Dec 2014) (Executive Order 13658).
- (xvi) [52.225-26](#), Contractors Performing Private Security Functions Outside the United States (Jul 2013) (Section 862, as amended, of the National Defense Authorization Act for Fiscal Year 2008; [10 U.S.C. 2302 Note](#)).
- (xvii) [52.226-6](#), Promoting Excess Food Donation to Nonprofit Organizations (May 2014) ([42 U.S.C. 1792](#)). Flow down required in accordance with paragraph (e) of FAR clause [52.226-6](#).
- (xviii) [52.247-64](#), Preference for Privately Owned U.S.-Flag Commercial Vessels (Feb 2006) ([46 U.S.C. Appx. 1241\(b\)](#) and [10 U.S.C. 2631](#)). Flow down required in accordance with paragraph (d) of FAR clause [52.247-64](#).

(2) While not required, the contractor may include in its subcontracts for commercial items a minimal number of additional clauses necessary to satisfy its contractual obligations.

52.252-1 Solicitation Provisions Incorporated by Reference (Feb. 1998)

This solicitation incorporates one or more solicitation provisions by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. The offeror is cautioned that the listed provisions may include blocks that must be completed by the offeror and submitted with its quotation or offer. In lieu of submitting the full text of those provisions, the offeror may identify the provision by paragraph identifier and provide the appropriate information with its quotation or offer. Also, the full text of a solicitation provision may be accessed

electronically at this/these address (es):

<http://farsite.hill.af.mil/>

52.212-1 Instructions to Offerors – Commercial Items (Apr. 2014)

52.212-2 Evaluation – Commercial Items (Oct. 2014)

52.212-3 Offeror Representations and Certifications—Commercial Items (May 2014)

An offeror shall complete only paragraphs (b) of this provision if the offeror has completed the annual representations and certificates electronically via <http://www.acquisition.gov> . If an offeror has not completed the annual representations and certifications electronically at the System for Award Management (SAM) website, the offeror shall complete only paragraphs (c) through (o) of this provision.

PART 11– INSTRUCTIONS TO THE OFFERORS

The provision 52.212-1 incorporated above is tailored as follows. QUOTATIONS are due May 3, 2016 at 12:00 p.m. (Eastern Time). Quotes shall be valid for 30 days. Send via email in native (Word/Excel) and PDF format to the Contract Specialist, DeLane Jones (Delane.jones@fda.hhs.gov). Send any QUESTIONS, via email, to the Contract Specialist no later than April 27, 2016 at 12:00pm (Eastern Time).

SAM: All interested offerors shall be registered in the System for Award Management (SAM), if the offeror is not registered in SAM, please visit <https://www.sam.gov>. You will need your Tax ID, DUNS Number and banking information. Vendors who are not registered in SAM will not be eligible for award.

PART 12 – GENERAL EVALUATION INFORMATION:

The provision 52.212-2 incorporated above is completed as follows. FDA will evaluate quotes received in response to this RFQ on using the low-price-technically-acceptable (LPTA) methodology. To be determined “Technically Acceptable”, the offeror must provide sufficient information in detail that allows the Government to evaluate that the contractor understands and has the ability to meet all the tasks listed in Part 3. The quote must outline all tasks in Part 3. FDA will make the award to the offeror whose quote is technically acceptable and whose overall price is the lowest.